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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,738	09/27/2001	Timothy J. O'Brien	022438.43865	3856

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EXAMINER	
REDDIG, PETER J	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,738	O'BRIEN ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-11 and 37* is/are pending in the application.

4a) Of the above claim(s) *37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20060808*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed August 23, 2006 in response to the Office Action of June 27, 2006 is acknowledged and has been entered. Previously pending claims 35 and 36 have been cancelled, claims 1 and 6 have been amended and new claim 37 has been added.

2. Claim 37 has been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to previously non-elected inventions.

3. Claims 1-3 and 5-11 are currently being examined.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The following rejections are being maintained:

New Grounds of Rejection

6. Claims 1-3 and 5-11are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a purified CA125 molecule, comprising: (a) an extracellular amino terminal domain, comprising amino acids #1-33 of SEQ ID NO: 299, amino acids #34-1593 of SEQ ID NO: 299, amino acids #1594-1605 of SEQ ID NO: 299, amino acids #1606-1617 of SEQ ID NO: 299, and amino acids #1618-1637 of SEQ ID NO: 299; (b) a multiple repeat domain, comprising SEQ ID NO: 150; and (c) a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain, and further comprising amino acids #1-11 of SEQ ID NO: 300; amino acids #12-33 of SEQ ID NO: 300; amino acids #34-82 of SEQ ID NO: 300; amino acids #83-133 of SEQ ID .NO: 300;. amino acids #134-156 of SEQ ID NO: 300; amino acids #157-212 of SEQ ID NO: 300; amino acids #213-225 of SEQ ID NO: 300; amino acids #226-253 of SEQ ID NO: 300;

and amino acids #254-284 of SEQ ID NO: 300 claimed in claim 1 has no clear support in the specification and the claims as originally filed.

Applicant argues that amended claim 1 is supported, e.g., by originally filed claims 1, 5-9, and 27; and at page 9, lines 16-17; FIG. 5(C); page 2, line 10; and page 26, line 21. A review of the originally filed claims 1, 5-9 and 27 revealed support for **Claim 1)** a CA125 molecule, comprising: (a) an extracellular amino terminal domain, comprising 5 genomic exons, wherein exons 1 comprises amino acids #1-33 of SEQ ID NO: 299, exon 2 comprises amino acids #34-1593 of SEQ ID NO: 299, exon 3 comprises amino acids #1594-1605 of SEQ ID NO: 299, exon 4 comprises amino acids #1606-1617 of SEQ ID NO: 299, and exon 5 comprises amino acids #1618-1637 of SEQ ID NO: 299; (b) a multiple repeat domain, wherein each repeat unit comprises 5 genomic exons, wherein exon 1 comprises amino acids #1-42 in any of SEQ ID NOS: 164 through 194; exon 2 comprises amino acids #43-65 in any of SEQ ID NOS: 195 through 221; exon 3 comprises amino acids #66-123 in any of SEQ ID NOS: 222 through 249; exon 4 comprises amino acids #124-135 in any of SEQ ID NOS: 250 through 277; and exon 5 comprises amino acids #136-156 in any of SEQ ID NOS: 278 through 298; and (c) a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain, and further comprising 9 genomic exons, wherein exon 1 comprises amino acids #1-11 of SEQ ID NO: 300; exon 2 comprises amino acids #12-33 of SEQ ID NO: 300; exon 3 comprises amino acids #34-82 of SEQ ID NO: 300; exon 4 comprises amino acids #83-133 of SEQ ID NO: 300; exon 5 comprises amino acids #134-156 of SEQ ID NO: 300; exon 6 comprises amino acids #157-212 of SEQ ID NO: 300; exon 7 comprises amino acids #213-225 of SEQ ID NO: 300; exon 8 comprises amino acids #226-253 of SEQ ID NO: 300; and exon 9 comprises amino acids

#254-284 of SEQ ID NO: 300; **claim 5)** the CA125 molecule according to claim 1, wherein the repeat domain comprises 156 amino acid repeat units which comprise epitope binding sites; **claim 6)** the CA125 molecule according to claim 5, wherein the epitope binding sites are located in the C-enclosure at amino acids #59-79 (marked C-C) in SEQ ID NO: 150 in FIG. 5; **claim 7)** the CA125 molecule according to claim 5, wherein the 156 amino acid repeat unit comprises O-glycosylation sites at positions #128, #129, #132, #133, #134, #135, #139, #145, #146, #148, #150, #151, and #156 in SEQ ID NO: 150 in FIG. 5C; **claim 8)** the CA125 molecule according to claim 5, wherein the 156 amino acid repeat unit comprises N-glycosylation sites at positions #33 and #49 in SEQ ID NO: 150 in FIG. 5C; **claim 9)** the CA125 molecule according to claim 5, wherein the 156 amino acid repeat unit comprises at least one conserved methionine (designated M) at position #24 in SEQ ID NO: 150 in FIG. 5C; and **claim 27)** a purified polypeptide of the CA125 gene, comprising an amino acid sequence selected from the group consisting of: (a) the amino acid sequences set forth in SEQ ID NOS: 11-48, 50, 68-80, 82, 146, 148, 149, 150, 151, and 153-158; (b) an amino acid sequence having at least 50% sequence identity to any one of the sequences in (a); (c) a conservative variant of any one of (a) to (b); and (d) a fragment of any one of (a) to (c), but did not reveal support for a purified CA125 molecule, comprising: (a) an extracellular amino terminal domain, comprising amino acids #1-33 of SEQ ID NO: 299, amino acids #34-1593 of SEQ ID NO: 299, amino acids #1594-1605 of SEQ ID NO: 299, amino acids #1606-1617 of SEQ ID NO: 299, and amino acids #1618-1637 of SEQ ID NO: 299; (b) a multiple repeat domain, comprising SEQ ID NO: 150; and (c) a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain, and further comprising amino acids #1-11 of SEQ ID NO: 300; amino acids #12-33 of SEQ ID NO: 300; amino acids

#34-82 of SEQ ID NO: 300; amino acids #83-133 of SEQ ID .NO: 300; amino acids #134-156 of SEQ ID NO: 300; amino acids #157-212 of SEQ ID NO: 300; amino acids #213-225 of SEQ ID NO: 300; amino acids #226-253 of SEQ ID NO: 300; and. amino acids #254-284 of SEQ ID NO: 300. A review of the specification at page 9, lines 16-17 revealed support for a typical repeat sequence corresponding to SEQ ID NO: 150, but did not reveal support for said purified CA125 molecule. A review of the specification at FIG. 5(C) revealed support for SEQ ID NO: 150, but did not reveal support for said purified CA125 molecule. A review of the specification at page 2, line 10 revealed support for highly purified high molecular weight CA125, but did not reveal support for said purified CA125 molecule. A review of the specification at page 26, line 21 revealed support for efforts to purify CA125, but did not reveal support for said purified CA125 molecule

Examiner's review of the specification did not reveal support for the newly added limitation as indicated above. Applicant is invited to submit evidence pointing to page and line number in the specification wherein support for the newly added limitation can be found. The subject matter claimed in claims 1 broadens the scope of the invention as originally disclosed in the specification.

7. Claims 1-3 and 5-11 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 1-3 and 5-11 are drawn to a purified CA125 molecule, comprising: (a) an extracellular amino terminal domain, comprising amino acids #1-33 of SEQ ID NO: 299, amino acids #34-1593 of SEQ ID NO: 299, amino acids #1594-1605 of SEQ ID NO: 299, amino acids #1606-1617 of SEQ ID NO: 299, and amino acids #1618-1637 of SEQ ID NO: 299; (b) a

multiple e repeat domain, comprising SEQ ID NO: 150; and (c) a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain, and further comprising amino acids #1-11 of SEQ ID NO: 300; amino acids #12-33 of SEQ ID NO: 300; amino acids #34-82 of SEQ ID NO: 300; amino acids #83-133 of SEQ ID .NO: 300; amino acids #134-156 of SEQ ID NO: 300; amino acids #157-212 of SEQ ID NO: 300; amino acids #213-225 of SEQ ID NO: 300; amino acids #226-253 of SEQ ID NO: 300; and. amino acids #254-284 of SEQ ID NO: 300. The claims as currently constructed do not limit the order in which the various amino acids sequences are joined together. Thus, the claim encompasses multiple variants of the CA125 molecule inclusive of numerous combinations of the various amino acid fragments recited.

As it is drawn to the DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or

> recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the instant specification may provide an adequate written description of a purified CA125 molecule comprising the various fragments of SEQ ID NO: 299 in any combination or order, a multiple repeat domain comprising SEQ ID NO: 150, and a carboxy terminal domain

comprising the various fragments of SEQ ID NO: 300 in any combination or order, per Lilly by structurally describing a representative number of the CA125 molecules comprising the various fragments of SEQ ID NO: 299 in any combination or order, a multiple repeat domain comprising SEQ ID NO: 150, and a carboxy terminal domain further comprising the various fragments of SEQ ID NO: 300 in any combination or order or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the CA125 molecule comprising the various fragments of SEQ ID NO: 299 in any combination or order, a multiple repeat domain comprising SEQ ID NO: 150, and a carboxy terminal domain further comprising the various fragments of SEQ ID NO: 300 in any combination or order in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any the CA125 molecule comprising the various fragments of SEQ ID NO: 299 in any combination or order, a multiple repeat domain comprising SEQ ID NO: 150, and a carboxy terminal domain further comprising the various fragments of SEQ ID NO: 300 in any combination or order, nor does the specification provide any partial structure of such CA125 molecule, nor any physical or chemical characteristics of the said CA125 molecule, nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses SEQ ID NO: 299, 150, and 300, this does not provide a description of the

CA125 molecule comprising the various fragments of SEQ ID NO: 299 in any combination or order, a multiple repeat domain comprising SEQ ID NO: 150, and a carboxy terminal domain further comprising the various fragments of SEQ ID NO: 300 in any combination or order that would satisfy the standard set out in Enzo.

The specification also fails to describe the CA125 molecule comprising the various fragments of SEQ ID NO: 299 in any combination or order, a multiple repeat domain comprising SEQ ID NO: 150, and a carboxy terminal domain further comprising the various fragments of SEQ ID NO: 300 in any combination or order by the test set out in Lilly. The specification describes only a SEQ ID NO: 299, 150, and 300. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of a purified CA125 molecule comprising the various fragments of SEQ ID NO: 299 in any combination or order, a multiple repeat domain comprising SEQ ID NO: 150, and a carboxy terminal domain further comprising the various fragments of SEQ ID NO: 300 in any combination or order that is required to make and use the claimed invention.

8. Claims 1-3 and 5-11 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 1-3 and 5-11 are drawn to a purified CA125 molecule, comprising: a multiple repeat domain, comprising SEQ ID NO: 150. The claims as currently constructed do not limit the

identity of the multiple repeats, the number of multiple repeats, or the order in which the various multiple repeat sequences are joined together. Thus, the claim encompasses multiple variants of the CA125 multiple repeat domain inclusive of numerous combinations of the multiple repeat units.

As it is drawn to the DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the instant specification may provide an adequate written description of a purified CA125 molecule, comprising: a multiple repeat domain, comprising SEQ ID NO: 150, per Lilly by structurally describing a representative number of the a purified CA125 molecules, comprising: a multiple repeat domain, comprising SEQ ID NO: 150 or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional

characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe a purified CA125 molecule, comprising: a multiple repeat domain, comprising SEQ ID NO: 150 in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of a purified CA125 molecule, comprising: a multiple repeat domain, comprising SEQ ID NO: 150, nor does the specification provide any partial structure of such CA125 molecule, nor any physical or chemical characteristics of said CA125 molecule, nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses various isolated multiple repeat domains, this does not provide a description of a purified CA125 molecule, comprising: a multiple repeat domain, comprising SEQ ID NO: 150 that would satisfy the standard set out in Enzo.

The specification also fails to describe a purified CA125 molecule, comprising: a multiple repeat domain, comprising SEQ ID NO: 150 by the test set out in Lilly. The specification only describes SEQ ID NO: 150 and other isolated repeat domains. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of a purified CA125 molecule comprising: a multiple repeat domain, comprising SEQ ID NO: 150 that is required to make and use the claimed invention.

9. Claims 1-3 and 5-11 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 1-3 and 5-11 are drawn to a purified CA125 molecule, comprising: a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain.

As it is drawn to the DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

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Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

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Thus, the instant specification may provide an adequate written description of a purified CA125 molecule, comprising: a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain, per Lilly by structurally describing a representative number of the purified CA125 molecules, comprising: a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional

characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe a purified CA125 molecule, comprising: a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of a purified CA125 molecule, comprising: a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain, nor does the specification provide any partial structure of such CA125 molecule, nor any physical or chemical characteristics of said CA125 molecule, nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification states that the CA125 molecule has a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain, this does not provide a description of a purified CA125 molecule, comprising: a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain that would satisfy the standard set out in Enzo.

The specification also fails to describe a purified CA125 molecule, comprising: a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain by the test set out in Lilly. The specification does not describe any purified CA125 molecule, comprising: a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of a purified CA125 molecule, comprising: a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain that is required to make and use the claimed invention.

10. All other objections and rejections recited in the Office action of June 27, 2006 are withdrawn.

11. No claims allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Peter J. Reddig, Ph.D.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER